IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently Amended): An oral multiparticulate pharmaceutical form comprising pellets having a size in the range from 50 to 2,500 μm, which comprise:

a) an inner matrix layer consisting essentially of a mucoadhesive polymer having a mucoadhesive effect, into which is embedded an active substance which is a peptide or a protein, which may include non-natural amino acid residue(s) ~~or a peptide or protein derivative or conjugate~~,

b) an outer film coating consisting essentially of an anionic polymer or copolymer,

wherein said multiparticulate pharmaceutical form is formulated so that

the contained pellets are released in the pH range of the stomach,

the outer coatings of the pellets are adjusted through the choice of the anionic polymer or copolymer or its formulation with excipients and its layer thickness such that the coating dissolves in pH ranges from 4.0 to 8.0 in the intestine within 15 to 60 min, so that the active substance-containing, mucoadhesive matrix layer is exposed and binds to the intestinal mucosa and releases the active substance there,

wherein the active substance content embedded in the matrix layer is a maximum of 40% by weight based on the weight of the polymer having a mucoadhesive effect, and

wherein the polymer having a mucoadhesive effect exhibits a mucoadhesive effect of η_b = 150 to 1000 mPa·s and a water uptake of from 10 to 750% in 15 min in a range of +/- 0.5 pH units relative to the pH at which the outer coating starts to dissolve and is selected from the group consisting of at least one of chitosan, a (meth)acrylate copolymer consisting of 20-40% by weight methyl methacrylate and 60 to 80% by weight methacrylic acid, a crosslinked polyacrylic acid, an uncrosslinked polyacrylic acid, an Na alginate, and a pectin.

Claim 2 (Withdrawn): The oral multiparticulate pharmaceutical form of claim 1, wherein the outer film coating is at least one material selected from the group consisting of cellulose glycolate (Duodcell®), cellulose acetate phthalate (CAP, Cellulosi acetas, PhEur, cellulose acetate phthalates, NF, Aquaterie®), cellulose acetate succinate (CAS), cellulose acetate trimeliate (CAT), hydroxypropylmethylcellulose phthalate (HPMCP, HP50, HP55), hydroxypropylmethylcellulose acetate succinate (HPMCAS-LF, -MF, -HF), polyvinyl acetate phthalate (PVAP, Sureteric®), vinyl acetate-vinylpyrrolidone copolymer (PVAc, Kollidon® VA64), vinyl acetate:crotonic acid 9:1 copolymer (VAC:CRA, Kollicoat® VAC) and shellack.

Claim 3 (Previously Presented): The oral multiparticulate pharmaceutical form of claim 1, wherein the outer film coating consists of a (meth)acrylate copolymer having a content of monomers having anionic groups of from 5 to 60% by weight.

Claim 4 (Previously Presented): The oral multiparticulate pharmaceutical form of claim 1, wherein the layer thickness of the outer coating is in the range from 20 to 200 μm.

Claim 5 (Withdrawn, Currently Amended): The oral multiparticulate pharmaceutical form of claim 1, ~~wherein the inner matrix further contains a C_6- to C_{20}-fatty acid and/or a C_6- to C_{20}-alcohol including their salts, ether, ester or amide derivatives and/or a lipid and/or a phospholipid and/or a lipid-soluble vitamin and/or~~ further comprising a protease inhibitor and/or a penetration promoter.

Claim 6 (Currently Amended): The oral multiparticulate pharmaceutical form of claim 1, wherein the mucoadhesive polymer in the inner matrix is chitosan and the active

pharmaceutical ingredient comprises Cetrorelix; and the outer coating comprises a copolymer of 50 wt% methylmethacrylate and 50 wt% methacrylic acid ~~(Eudragit® L)~~.

Claim 7 (Previously Presented): The oral multiparticulate pharmaceutical form of claim 6, wherein the inner matrix contains as polymer having a mucoadhesive effect a chitosan which is employed together with an acid or a buffer system, which is located in the matrix or in or on a core onto which the matrix is applied.

Claim 8 (Previously Presented): The oral multiparticulate pharmaceutical form of claim 7, wherein the inner matrix layer contains chitosan and is adjusted to pH 5.0 to 5.5 by means of an acid or a buffer system, and is combined with an outer film coating which starts to dissolve in the range from pH 6.0 to 8.0.

Claim 9 (Previously Presented): The oral multiparticulate pharmaceutical form of claim 1, wherein the active substance is a protein or a peptide having an average molecular weight M_w of less than 3,000 Da.

Claim 10 (Previously Presented): The oral multiparticulate pharmaceutical form of claim 9, wherein the active substance is selected from the group consisting of abarelix angiogenesis II, anidulafungin, antide, argipressin, azaline and azaline B, bombesin antagonist, bradykinin, buserelin, cetrorelix, cyclosporin A, desmopressin, detirelix, encephalins (Leu-, Met-) ganirelix, gonadorelin, goserelin, growth hormone secretagogue, micafungin, nafarelin, leuprolide, leuprorelin, octreotide, orntide, oxytocin, ramorelix, secretin, somatotropin, terlipressin, tetracosactide, teverelix, triptorelin, thyroliberin, thyrotropin, vasopressin and mixtures thereof.

Claim 11 (Withdrawn): The oral multiparticulate pharmaceutical form of claim 9, wherein the inner matrix layer additionally contains a C_6- to C_{20}-fatty acid and/or a C_6- to C_{20}-alcohol including their salts, ether, ester or amide derivatives and/or a lipid and/or a phospholipid and/or a lipid-soluble vitamin.

Claim 12 (Withdrawn): The oral multiparticulate pharmaceutical form of claim 1, wherein the active substance is a protein or peptide having an average molecular weight M_w of from 3,000 to 10,000.

Claim 13 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 12, wherein the active substance is at least one substance selected from the group consisting of calcitonin, corticotrophin, endorphins, epithelial growth factor, glucagon, insulin, novolin, parathyroid hormone, relaxin, pro-somatostatin and salmon secretin.

Claim 14 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 12 wherein the matrix layer comprises a C_6- to C_{20}-alcohol including their salts, ether, ester or amide derivatives and/or a lipid and/or a phospholipid and/or a lipid-soluble vitamin and/or a protease inhibitor.

Claim 15 (Withdrawn): The oral multiparticulate pharmaceutical form of claim 1, wherein the active substance is a protein or peptide having an average molecular weight M_w of more than 10,000.

Claim 16 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 15, wherein the active substance is at least one substance selected from the group consisting of interferon (alpha, beta, gamma), interleukins (IL1, IL2), somatotropin, erythropoietin, tumor necrosis factor (TNF alpha, beta), relaxin, endorphin, dornase alpha, follicle stimulating hormone (FSH), human chorionic gonadotropin (HCG), human growth hormone release factor (hGRF), luteinizing hormone (LH) and epidermal growth factor.

Claim 17 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 15 wherein the matrix layer comprises a C_6- to C_{20}-fatty acid and/or a C_6- to C_{20}-alcohol including their salts, ether, ester or amide derivatives and/or a lipid and/or a phospholipid and/or a lipid-soluble vitamin and/or a protease inhibitor and/or a penetration promoter.

Claim 18 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 1, wherein a separating layer is applied between the active substance-containing matrix layer and the outer film coating layer.

Claim 19 (Withdrawn): A process for producing an oral multiparticulate pharmaceutical form as claimed in claim 1, comprising

a) producing an inner matrix layer comprising an active substance, which is a peptide or a protein, and a polymer having a mucoadhesive effect and, where appropriate, further pharmaceutically usual excipients by means of spray application onto a core or by rotagglomeration, precipitation or spray processes without a core, and subsequently,

b) applying an outer film coating consisting essentially of an anionic polymer or copolymer, which may optionally be formulated with pharmaceutically usual excipients, especially plasticizers, by means of spray application so that active substance-containing, enveloped pellets are obtained, and

c) processing the resulting pellets by means of pharmaceutically usual excipients in a manner known per se to a multiparticulate pharmaceutical form, in particular to pellet-containing tablets, minitablets, capsules, sachets or reconstitutable powders, which are formulated so that the contained pellets are released in the pH range of the stomach.

Claim 20 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 1, wherein the active substance is embedded in a lipophilic matrix which has a melting point above 37°C, and the active substance-containing lipophilic matrix is embedded in the matrix composed of the polymer having a mucoadhesive effect.

Claim 21 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein the active substance and the substance or substances forming the lipophilic matrix differ in their solubility in water according to DAB 10 and not more than +/- 50%, and/or differ in their partition coefficient according to annex V to directive 67/548/EEC, A.8 by not more than +/- 60%, and/or differ in their HLB measured by the method of Marszall not more +/- 80%.

Claim 22 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein an active substance which has a solubility in water according to DAB 10 of at least 30 parts by volume of water for one part by weight of active substance is present.

Claim 23 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 22, wherein the active substance is at least one substance selected from the group consisting of peptide antibiotics, immunosuppressants, LHRH antagonists and immunomodulators.

Claim 24 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 22, wherein the active substance is at least one substance selected from the group consisting of abarelix, angiotensin II, anidulafungin, antide, argipressin, azaline and azaline B, bombesin antagonist, bradykinin, buserelin, calcitonin, cetrorelix, cyclosporin, cyclosporin A, desmopressin, detirelix, erythropoietin, encephalins (Leu-, Met-) ganirelix, gonadorelin, goserelin, growth hormone secretagogue, insulin, interferon (alpha, beta, gamma), interleukins (IL1, IL2), micafungin, nafarelin, leuprolide, leuprorelin, octreotide, orntide, oxytocin, parathyroid hormone, ramorelix, secretin, somatotropin, terlipressin, tetracosactide, teverelix, triptorelin, thyroliberin, thyrotropin, tumor necrosis factor (TNF alpha, beta) and vasopressin.

Claim 25 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein the substance or substances forming the lipophilic matrix, and the polymer having a mucoadhesive effect either have the same ionic property or, in the event of opposed ionic properties, the polymer having a mucoadhesive effect is present in at least 50% neutralized form.

Claim 26 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein the lipophilic matrix consists of 80 to 100% by weight of a substance

having an HLB of from 0 to 15 or of a mixture of substances having an average HLB of from 0 to 15, and may comprise from 0 to 20% by weight of pharmaceutically usual excipients, stabilizers, thickeners or adsorbents.

Claim 27 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein the substance or the substances forming the lipophilic matrix are at least one substance selected from the group consisting of oils, fats, mono-, di- or triglycerides, fatty acids, fatty alcohols, especially C_6 to C_{20}-fatty acid and/or a C_6- to C_{20}- alcohol including their salts, ether, ester or amide derivatives, phospholipids, lecithins, emulsifiers, lipoids, lipid-soluble vitamins and surfactants.

Claim 28 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein the lipophilic matrix comprises one of the following lipid preparations: (Imwitor 308) glyceryl monocaprylates having a monoester content of > 80%, (Imwitor 312) glyceryl monolaurates having a monoester content of > 90%, (Imwitor 491) glycerol monostearates (C_{16} + C_{18}) having a monoester content of > 90%, (Imwitor 900 P) glycerol monostearate having a monoester content of 40-55% and a C_{18} content of 40-60%, (Imwitor 900 K) glycerol monostearate, having a monoester content of 40-55% and a C_{18} content of 60-80%, (Imwitor 742) medium chain-length C_8 and C_{10} glycerides having a monoester content of 45-55%, (Imwitor 928) partial glycerides of saturated vegetable C_{10}-C_{18} fatty acids having a main content of C_{12}, and having a monoester content of 34-36%, C_8 and C_{10} glycerides, Na caprylate or Na capriate.

Claim 29 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein the active substance is at least 10% soluble in the lipophilic matrix.

Claim 30 (Withdrawn): The oral multiparticulate pharmaceutical form as claimed in claim 20, wherein the content of active substance-containing lipophilic matrix in the inner matrix layer a) is from 5 to 50% by weight.

Claim 31 (Withdrawn): A process for producing an oral multiparticulate pharmaceutical form as claimed in claim 20, comprising

a) producing the active substance-containing lipophilic matrix by suspending and/or dissolving the active substance with the substance(s) which form the lipophilic matrix and, where appropriate, further pharmaceutically usual excipients by vigorously mixing or melting the ingredients,

b) producing pre-pellets (pellet cores) by spray application of the mucoadhesive polymer mixed with the active substance-containing lipophilic matrix onto a core or by rotagglomeration, precipitation or spray processes without a core,

c) producing pellets by spray application of a coating of the anionic polymer or copolymer, which may optionally comprise admixtures of pharmaceutically usual excipients, especially plasticizers and release agents, from a dispersion or organic solution onto the pre-pellets from step b),

d) producing a multiparticulate pharmaceutical form by filling or incorporating the pellets from step c) in a manner known per se, where appropriate with use of pharmaceutically usual excipients, in particular by processing to pellet-containing tablets, minitablets, capsules, sachets or reconstitutable powders.

Claim 32 (Withdrawn): The process for producing an oral multiparticulate pharmaceutical form as claimed in claim 31, wherein steps a) and b) comprise

a) producing the inner matrix layer by preparing an emulsion, dispersion or solution of the active substance with the substance(s) for the lipophilic matrix, and where appropriate further pharmaceutically usual excipients by vigorously mixing the ingredients in water and producing an oil-in-water preparation having an average particle size of not more than 60 μm,

b) producing pre-pellets by spray application of the oil-in-water preparation from step a) onto the mucoadhesive polymer which may optionally comprise admixtures of further pharmaceutically usual excipients, where the ingredients are in the form of a micronized powder, by rotagglomeration, extrusion or granulation.

Claim 33 (Previously Presented): The oral multiparticulate pharmaceutical form of claim 1, which does not contain gelatin in the inner matrix layer.

Claim 34 (Previously Presented): A composition containing pellets ranging in size from 50 to 2,500 μm that comprise:

a inner matrix comprising 40 wt.% or less of an active pharmaceutical ingredient and a polymer having a mucoadhesive effect of at least η_β of 150 to 1,000 mPa·s and a water uptake ranging from 10 to 750% in 15 min at a pH between 5.5 and 7.2, and

an outer coating of anionic polymer or anionic copolymer;

wherein said particles do not have a layer separating the inner matrix and outer coating, and do not have a mucoadhesive lipophilic matrix embedded in the inner matrix;

wherein the outer coating dissolves at a pH ranging from 5.5 to 7.2 within 15 to 60 mins.

Claim 35 (Currently Amended): The composition of claim 34, wherein the mucoadhesive inner matrix comprises:

chitosan and the active pharmaceutical ingredient comprises Cetrorelix; and

the outer coating comprises a copolymer of 50 wt% methylmethacrylate and 50 wt% methacrylic acid ~~(Eudragit® L)~~.